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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,528	09/10/2003	Cary James Miller	215105.01400	1959

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EXAMINER	
ALEXANDER, LYLE	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
03/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,528	MILLER ET AL.	
	Examiner	Art Unit	
	Lyle A. Alexander	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,63 and 64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,63 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 and 63-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification does not require the slidably moving sealing element to be placed over the orifice prior to insertion into the reader as presently claimed.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-24 and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelin (USP 5,821,399) in view of Yokota et al. (USP 5,846,490).

Zelin teach a method and apparatus for the testing of biological fluids. Figures 2-5 teach a device comprising a housing comprising at least one planar surface, a fluid addition orifice in fluid communication with an internal holding chamber, a capillary that stops the added fluid from entering the analysis chamber until it is actuated which has been read on the claimed "expelling a metered portion of the sample through the capillary stop." The insertion of the device(10) into the reader(150) performs the

claimed function of "... displaces any excess fluid sample away from the orifice, seals the fluid sample within the holding chamber ...".

Zelin is silent to wiping away excess sample prior to placement of the cartridge into the reading device.

Yokota et al. teach in column 2 lines 17-25 it is conventional to remove the excess liquid from a test device prior to placing the device in an analyzer. This is advantages because excess sample spilled inside the analyzer could contaminate subsequent tests and skew the results. Additionally, excess sample in the analyzer could damage the analyzer.

It would have been within the skill of the art to modify Zelin in view of Yokota et al. and remove the excess fluid prior to inserting into the analyzer to gain the above advantages.

Zelin in view of Yokota et al. are silent to the claimed plastic and the claimed volumes.

The court decided In re Boesch (205 USPQ215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The selection of a particular plastic or the volume of analysis are both result effective variable that have well known and expected results. Plastics are well known for being inert, inexpensive, lightweight and durable. The selection of the analysis volume is based upon the sample easily obtainable and the minimization of reagent to minimize the cost of each test.

It would have been within the skill of the art to further modify Zelin and use a polyester, ABS or acetal plastic as optimization of a result effective variable and to gain the above advantages. It would have been within the skill of the art to further modify Zelin and use the claimed volumes of 5-50 microliters as well as the claimed orifice in the range of 1-2 mm as optimization of a result effective variable and to gain the above advantages.

Claims 1-24 and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (USP 7,419,821).

Davis et al. is available as prior art because the inventive entity is different even though there is one invention in common. Davis et al. teach the same structure as presently claimed. The method is best summarized in column 20-21 lines 58-3 respectively which is indistinguishable from that presently claimed.

Davis et al. are silent to wiping away excess sample prior to placement of the cartridge into the reading device.

Yokota et al. teach in column 2 lines 17-25 it is conventional to remove the excess liquid from a test device prior to placing the device in an analyzer. This is advantages because excess sample spilled inside the analyzer could contaminate subsequent tests and skew the results. Additionally, excess sample in the analyzer could damage the analyzer.

It would have been within the skill of the art to modify Davis et al. in view of Yokota et al. and remove the excess fluid prior to inserting into the analyzer to gain the above advantages.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1797

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Primary Examiner, Art Unit 1797